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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,319

07/29/2005

Patrice Hildgen

9680.258USWO

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23552 7590 06/26/2008

MERCHANT & GOULD PC

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MINNEAPOLIS, MN 55402-0903

EXAMINER

BERMAN, SUSAN W

ART UNIT

PAPER NUMBER

1796

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DELIVERY MODE

06/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,319	Applicant(s) HILDGEN ET AL.	
	Examiner /Susan W. Berman/	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10-4-2004</u> . | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-21, 37-40 and 41-44 partially, drawn to a polymeric biodegradable nanosphere comprising a polyester-polyethylene multiblock copolymer, a method for delivering a pharmaceutical compound into a mammal by administration thereof and a method for preparation thereof.

Group II, claim(s) 22-28, drawn to a polyester-polyethylene multiblock copolymer of formula (III): $ABA-B'-(ABA-B')_n-ABA$ (III), wherein A is a polyester, B is a polyethylene, B' is a dicarboxylic polyethylene and $n \geq 2$ and a method for preparing the polyester-polyethylene multiblock copolymer of formula (III).

Group III, claim(s) 29-36, drawn to an improved method for preparing a PLA-PEG-PLA multiblock copolymer of formula (I): $ABA-(c-ABA)_n-c-ABA$ (I), wherein ABA is a PLA-PEG-PLA triblock, c is a carboxylic diacid and $n \geq 2$.

Group IV, claim(s) 41-44 partially, drawn to a method for preparing polymeric biodegradable nanospheres from an emulsion comprising the steps of (i) preparing an organic internal phase comprising a pharmaceutical compound and a blend of polymers and a polyester, (ii) preparing an aqueous external phase, (iii) injecting both phases into a homogenization chamber having an outlet, (iv) evaporating and/or extracting the phases of step (iii) and (v) collecting the polymeric nanospheres by centrifugation or dialysis.

The inventions listed as Groups I to IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Polyester-polyethylene multiblock copolymeric nanospheres are known in the art and it is known in the art to use polyester-polyethylene multiblock copolymeric nanospheres for drug delivery. Therefore, the use of polyester-polyethylene multiblock copolymers for nanospheres or polyester-polyethylene multiblock copolymeric nanospheres for drug delivery does not function as a special technical feature to provide a single inventive concept uniting the groups of claims set forth above.

US 5,683,723 discloses biodegradable nanospheres comprising a PLA-PEG diblock copolymer.

Art Unit: 1796

US 6,139,870 discloses nanospheres comprising a PLA-PEG diblock copolymer and an anti-cancer agent.

WO 0112718 discloses polymeric miscelles of PEG-PLA-PEG or PEG-PLDO-PEG triblock copolymers and anti-cancer drugs.

XP 000783648 discloses nanospheres of PLA-POE-PLA triblock copolymer and progesterone.

XP 002257858 discloses nanospheres of polycaprolactone-PEG-polycaprolactone triblock copolymers and clonazepam.

XP 002257860 discloses nanospheres comprising PLA-PEG copolymer and an anti-cancer drug.

A telephone call was made to Gregory A. Sebald on June 6, 2008, but did not result in an election.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 1796

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SB
6/21/2008

/Susan W Berman/
Primary Examiner
Art Unit 1796